

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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ADMINISTRATION

**In re Application of:**

Jones et al.

**Serial No.:** 10/644,256

**Filed:** August 20, 2003

**For:** EFFICIENT PRODUCTION OF IgA  
IN RECOMBINANT MAMMALIAN  
CELLS

**Examiner:** M. Joike

**Group Art Unit:** 1636

**Attorney Docket No.:** 2578-6077US

NOTICE OF EXPRESS MAILING

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**RENEWED PETITION UNDER 37 C.F.R. §§ 1.78(a)(3), 1.78(a)(6), AND 1.55(c) FOR  
ACCEPTANCE OF UNINTENTIONALLY DELAYED PRIORITY CLAIMS**

Mail Stop Legal PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In response to the Decision on Second Renewed Petition, received on August 23, 2010, the applicants respectfully renew their petition under 37 C.F.R. § 1.78(a)(3); 37 C.F.R. § 1.78(a)(6); and 37 C.F.R. § 1.55(c) for the acceptance of their unintentionally delayed priority claims.

**Factual Background:**

On November 16, 2006, the applicants submitted an initial request for the acceptance of an unintentionally delayed priority claim in the context of a response to an Office Action dated

August 23, 2006. The request was accompanied by the requisite fee under 37 C.F.R. § 1.17(t). The request was subsequently denied in an Office Action dated February 28, 2007. Thereafter, the applicants submitted a formal Petition for Acceptance of an Unintentionally Delayed Priority Claim on June 14, 2007. This Petition was dismissed in a Decision dated September 30, 2008. Subsequently, the applicants filed a Renewed Petition on November 24, 2008. This Renewed Petition was dismissed on July 7, 2009.

On August 21, 2009, the applicants filed a further renewed Petition under 37 C.F.R. § 1.78(a)(6) for Acceptance of Unintentionally Delayed Priority Claims. The renewed Petition was directed to the addition of two sets of priority claims. The first set of priority claims concerned domestic priority claims under 35 U.S.C. §§ 120 and 365(c), directed to two international applications, together with associated priority claims to a US provisional application under 35 U.S.C. § 119(e). The second set of priority claims were directed to a domestic priority claim to an international application under 35 U.S.C. §§ 120 and 365(c), together with an associated priority claim to a foreign application under 35 U.S.C. § 119(a)-(d).

Applicants' Petition was dismissed in a Decision dated March 9, 2010. In his Decision, the Legal Examiner determined, pursuant to 37 C.F.R. §§ 1.178(a)(3) and 1.78(a)(6), the following with respect to the first set of priority claims, namely:

1. The Petition was filed after November 29, 2000, and therefore the Petition was properly submitted after the time periods specified in 37 C.F.R. §§ 1.78(a)(2)(ii) and 1.78(a)(2)(i), and therefore the Petition was a proper petition under 37 C.F.R. §§ 1.78(a)(3) and 1.78(a)(6).
2. The surcharge required by 37 C.F.R. § 1.17(t) was timely submitted;
3. The Statement that the entire delay between the date the claim was due under 37 C.F.R. §§ 1.78(a)(2)(ii) and 1.78(a)(5)(ii) and the date the claim was filed was unintentional was properly submitted.

With respect to the final requirement under 37 C.F.R. 1.78, namely that the applicants provide the reference required by 35 U.S.C. §§ 120 and 119(e), and 37 C.F.R. §§ 1.78(a)(2)(i)

and 1.78(a)(5)(i), to the prior filed application, the Legal Examiner determined that the applicants had submitted an acceptable reference with respect to the claim of priority under 35 U.S.C. §§ 120 and 365(c) to international application PCT/EP2003/007690, and through that international application under 35 U.S.C. § 119(e) to U.S. provisional application 60/397,066. It follows that with respect to the priority claim directed to PCT/EP2003/007690 and U.S. provisional application 60/397,066., the Legal Examiner determined that the Petition had met all of the statutory requirements for an acceptance of the priority claim.

With respect to the final requirement of providing the reference to the domestic priority claim under 35 U.S.C. §§ 120 and 365(c) with respect to international application PCT/EP03/50201, and through that international application under 35 U.S.C. § 119(e) to U.S. provisional application 60/397,066, the Legal Examiner determined that the applicants had failed to submit a proper reference. Specifically, the Legal Examiner noted that international application PCT/EP03/50201 was not published by the International Bureau (IB), and therefore it was not possible, given the present record, to ascertain whether the instant application was filed during the pendency of international application PCT/EP03/50201. In reaching his decision, the Legal Examiner cited MPEP § 1895.01 and its requirement that the applicants certify that the international application was not withdrawn or considered withdrawn prior to the filing date of the national application which claimed the benefit under 35 U.S.C. §§ 120 and 365(c).

In his Decision, the Legal Examiner indicated that should the applicants wish to renew their petition, the applicants would be required to provide a copy of PCT/EP03/50201 together with a certification and documentary support confirming that international application PCT/EP03/50201 was not withdrawn prior to the filing date of the instant application. Furthermore, the Legal Examiner indicated that the applicants would also need to establish that PCT/EP03/50201 named at least one inventor in common with the instant application. As a final requirement, the Legal Examiner further required that the applicants provide a substitute amendment containing a proper reference to the prior-filed international applications and the provisional application.

Regarding the second set of priority claims, *i.e.* the priority claim directed to PCT/EP03/50201 and its associated claim to foreign priority claim under 35 U.S.C. § 119(a)-(d) to EP application 02077953.4, the Legal Examiner first determined that the proper basis of

applicants' petition was 35 U.S.C. § 365(b) instead of 35 U.S.C. § 365(c). The Legal Examiner further concluded that such a petition, in order to be granted, must meet the provisions of 37 C.F.R. § 1.55(c). In analyzing the second set of priority claims under 37 C.F.R. § 1.55(c), the Legal Examiner determined as follows:

1. The instant application was filed after November 29, 2000, and therefore the Petition was properly submitted after the time periods specified in 37 C.F.R. § 1.55(c) and therefore the Petition was a proper petition under 37 C.F.R. § 1.55(c).
2. Applicants' priority claim, as identified in the Declaration filed on November 20, 2006, in the instant application, had properly identified the prior foreign application for which priority was claimed by application number, country and filing date.
3. The surcharge required by 37 C.F.R. § 1.17(t) was timely paid.
4. The Statement that the entire delay, between the date the claim was due under 37 C.F.R. § 1.55(a)(1) and the date the claim was filed, was unintentional was properly submitted.

With respect to the final requirement, namely that the nonprovisional application must be filed within 12 months of the filing date of the referenced foreign application, *i.e.* the filing date of EP application 02077953.4, the Legal Examiner determined that the applicants had failed to meet their obligation. Specifically, the Legal Examiner determined that the filing date of the instant application, namely August 20, 2003, was not within 12 months of the July 18, 2002, filing date of EP application 02077953.4. In reaching his decision, the Legal Examiner noted that notwithstanding his determination, this final requirement would be satisfied in a renewed petition if applicants could successfully add a claim of domestic priority to prior filed international application PCT/EP2003/007690 or international application PCT/EP03/50201, since the filing date of the EP application 02077953.4 would then be within 12 months of the filing date of either of these two international applications.

On May 17, 2010, the applicants filed yet a further renewed Petition under 37 C.F.R. §§ 1.78(a)(3), 1.78(a)(6), and 1.55(c) for Acceptance of Unintentionally Delayed Priority Claims together with an Amendment under 37 C.F.R. § 1.116 requesting, *inter alia*, that the Office amend the Specification to incorporate references to priority documents. This renewed Petition was dismissed in a Decision on Second Renewed Petition, mailed August 23, 2010. As stated in this Decision, the Legal Examiner determined that the Petition could not be granted until appropriate references to the priority documents were introduced into the application. Therefore, since the Examiner indicated that she would not enter the Amendment under 37 C.F.R. § 1.116 that had been submitted with the Petition, and the case had been finally rejected, the Office determined that the Petition could not be granted.

On August 31, 2010, the applicants' attorney, Alexander Stein, participated in a telephone conference with Richard M. Ross of the Office of PCT Legal Administration. The applicants are extremely grateful for the courtesy shown by the Office in conducting this interview. During the interview, Mr. Ross indicated that the Office could not procedurally grant the Petition until prosecution had been reopened by the filing of a Request for Continued Examination, and an Amendment incorporating appropriate references to the priority documents into the application was also submitted. It is the applicants' understanding from the interview that additional copies of the materials submitted with the last renewed petition (*i.e.*, a certified copy of PCT International Patent Application No. PCT/EP03/50201; a copy of the Receipt of Electronic Submission for PCT/EP03/50201; a copy of the Invitation to Pay Prescribed Fees for PCT/EP03/50201; and a copy of the Notification that International Application Considered to be Withdrawn for PCT/EP03/50201) do not need to be re-submitted with the present Petition. If this understanding is incorrect, the Office is respectfully requested to contact the applicants' attorney at the phone number provided herein. The applicants believe that the foregoing adequately describes the interview. If, however, the Office believes more detail to be desirable, the Office is kindly requested to contact the applicants' attorney, and more detail will be provided to the extent available.

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**Applicants' Renewed Petition Regarding the Priority Claim to PCT/EP2003/007690 and the Accompanying Priority Claim to U.S. Provisional 60/397,066:**

Pursuant to 37 C.F.R. § 1.78(a)(3) and 37 C.F.R. § 1.78(a)(6), applicants hereby renew their petition to be afforded, under 35 U.S.C. § 120, a claim of domestic priority to PCT International Patent Application No. PCT/EP2003/007690, and through this international application a claim of domestic priority under 35 U.S.C. §§ 119(e) and 365(c) to U.S. Provisional application 60/397,066. In support of this petition applicants submit as follows:

1. Applicants' application was filed on August 20, 2003, and was therefore filed after November 29, 2000. Accordingly, the applicants' claims are submitted after the expiration of the periods specified in 37 C.F.R. §§ 1.78(a)(2)(ii) and 1.78(a)(5)(ii). It follows there from that the instant petition is proper under 37 C.F.R. §§ 1.78(a)(3) and 1.78(a)(6).
2. The references to the prior filed applications, required by 35 U.S.C. §§ 120 and 119(e) and 37 C.F.R. §§ 1.78(a)(2)(i) and 1.78(a)(5)(i), are properly set forth in the Amendment to the specification of the application which is being filed simultaneously herewith. A copy of the Amendment is attached hereto as Exhibit A. The applicants respectfully submit that the Amendment properly identifies International Patent Application No. PCT/EP2003/007690 and its continuation-in-part relationship to the instant application. Furthermore, the Amendment also properly identifies U.S. Provisional application 60/397,066 and the 35 U.S.C. § 119(e) claim of priority to that provisional application through International Patent Application No. PCT/EP2003/007690. In view of the submission of this Amendment, the applicants submit that the reference requirements under 35 U.S.C. §§ 119(e), 120, and 365(c) and 37 C.F.R. §§ 1.78(a)(3) and 1.78(a)(6) have been satisfied.
3. The surcharge required under 37 C.F.R. § 1.17(t) was previously submitted in

conjunction with applicants' prior request dated November 16, 2006.

4. Applicants hereby state that the entire delay between the date the claim was due under 37 C.F.R. §§ 1.78(a)(2)(ii) and 1.78(a)(5)(ii) and the date that the claim was filed was unintentional.

In view of the prior indications of the Legal Examiner, the applicants respectfully submit that the above petition for the acceptance of a priority claim to International Patent Application No. PCT/EP2003/007690, and through this international application, the priority claim to U.S. Provisional application 60/397,066, should now be in acceptable form. Reconsideration of the petition with respect to these priority claims is therefore requested.

**Applicants' Renewed Petition Regarding the Priority Claim to PCT/EP2003/50201 and the Accompanying Priority Claim to U.S. Provisional 60/397,066:**

Pursuant to 37 C.F.R. § 1.78(a)(3) and 37 C.F.R. § 1.78(a)(6), the applicants hereby renew their petition to be afforded, under 35 U.S.C. § 120, a claim of domestic priority to PCT International Patent Application No. PCT/EP2003/50201, and through this international application, a claim of domestic priority under 35 U.S.C. §§ 119(e) and 365(c) to U.S. Provisional application 60/397,066. In support of this petition, the applicants submit as follows:

1. Applicants' application was filed on August 20, 2003, and was accordingly filed after November 29, 2000. Therefore, the applicants' claims are submitted after the expiration of the periods specified in 37 C.F.R. §§ 1.78(a)(2)(ii) and 1.78(a)(5)(ii). It follows that the instant petition is proper under 37 C.F.R. §§ 1.78(a)(3) and 1.78(a)(6).
2. The references to the prior filed applications, required by 35 U.S.C. §§ 120 and 119(e) and 37 C.F.R. §§ 1.78(a)(2)(i) and 1.78(a)(5)(i), are properly set forth in the Amendment to the specification of the application which is being filed simultaneously

herewith. As noted previously, a copy of the Amendment is attached hereto as Exhibit A. The applicants respectfully submit that the Amendment properly identifies International Patent Application No. PCT/EP2003/50201 and its continuation-in-part relationship to the instant application. Furthermore, the Amendment also properly identifies U.S. Provisional application 60/397,066 and the claim of priority to that provisional application under 35 U.S.C. §§ 119(e) and 365(c) through International Patent Application No. PCT/EP2003/50201.

In his prior decision, the Legal Examiner had indicated that a proper reference to International Patent Application No. PCT/EP2003/50201 and U.S. Provisional application 60/397,066 would require the applicants, under the provisions of MPEP § 1895.01, to certify that International Patent Application No. PCT/EP2003/50201 was pending as of the filing date of the instant application; *i.e.* that the international application was pending on August 20, 2003. Responsive to the Legal Examiner's request, the applicants hereby affirmatively certify that International Patent Application No. PCT/EP2003/50201 was a validly pending application on August 20, 2003. In support of their certification, the applicants reference the as-filed copy of International Patent Application No. PCT/EP2003/50201, certified by the European Patent Office (EPO) and submitted as Exhibit B with the Petition filed on May 17, 2010. The EPO was the International Receiving Office for International Patent Application No. PCT/EP2003/50201. A review of the certified copy will verify that the application was filed on May 27, 2003, with the EPO. Further confirmation of this filing was submitted with the Petition filed on May 17, 2010, in the form of a Receipt of Electronic Submission, attached thereto as Exhibit C.

With regard to the pendency of International Patent Application No. PCT/EP2003/50201, as noted on the Receipt of Electronic Submission, this application was initially filed without the payment of a filing fee. On August 4, 2003, the EPO issued an Invitation to Pay Prescribed Fees Together with a Late Payment Fee under the provisions of PCT Rule 16bis. A copy of this Invitation was submitted with the Petition filed on May 17, 2010, as Exhibit D. This Invitation provided a one month period, *i.e.*



until September 4, 2003, for the applicants to pay the requested filing fees. Applicants did not submit the requested filing fees prior to the deadline. On September 23, 2003, the EPO formally issued a Notification That International Application Considered To Be Withdrawn pursuant to PCT Article 14(1) or (3) and Rule 29.1 or 92.4(g)(i). A copy of this Notification was submitted with the Petition filed on May 17, 2010, as Exhibit E. The issuance of this Notification acknowledged the withdrawal of this application effective September 23, 2010.

As documented by the Exhibits B-D, submitted with the Petition filed on May 17, 2010, International Patent Application No. PCT/EP2003/50201 was validly filed on May 27, 2003 and after review by the EPO PCT Receiving Office was accorded an international filing date. Moreover, International Patent Application No. PCT/EP2003/50201 was pending from its date of filing until September 23, 2003, when it was formally withdrawn by the European Patent Office. The instant application was filed during the one month period provided to the applicants under PCT Rule 16bis to pay the filing fee in International Patent Application No. PCT/EP2003/50201. It follows that International Patent Application No. PCT/EP2003/50201 was validly pending on August 20, 2003, when the instant application was filed. In this regard, the applicants respectfully direct the Legal Examiner's attention to paragraph 6.009 of the PCT User's Guide.

With regard to the Legal Examiner's requirement that applicants confirm that at least one inventor is commonly named on both the instant application and International Application No. PCT/EP03/50201, the Legal Examiner may note from the frontpiece of the certified copy of the as filed application that at least one inventor, namely Abraham Bout, is named in both International Patent Application No. PCT/EP2003/50201 and the instant application.

In view of the showing that International Patent Application No. PCT/EP2003/50201 was pending on the filing date of the instant application, and further given the identification of a common inventor on both international application no. PCT/EP03/50201 and the instant application, the applicants respectfully submit that the requirement of a reference to the prior filed applications as required by 35 U.S.C. §§ 120

and 119(e) and 37 C.F.R. §§ 1.78(a)(2)(i) and 1.78(a)(5)(i) has now been satisfied for purposes of the present petition.

3. The surcharge required under 37 C.F.R. § 1.17(t) was previously submitted in conjunction with applicants' prior Petition dated November 16, 2006.

4. Applicants hereby state that the entire delay between the date the claim was due under 37 C.F.R. §§ 1.78(a)(2)(ii) and 1.78(a)(5)(ii) and the date that the claim was filed was unintentional.

In view of the prior indications of the Legal Examiner, together with the facts set forth above, the applicants respectfully submit that the petition for the acceptance of a priority claim under 35 U.S.C. §§ 120 and 365(c) to International Patent Application No. PCT/EP2003/50201, and through this international application under 35 U.S.C. § 119(e) to U.S. Provisional application 60/397,066, should now be in acceptable form. Reconsideration of the petition with respect to these priority claims is therefore requested.

**Applicants' Petition Regarding the Priority Claim to PCT/EP2003/50201 and the Accompanying Priority Claim to EP02077953.4:**

Pursuant to 37 C.F.R. § 1.78(a)(3) and 37 C.F.R. § 1.78(a)(6), the applicants hereby renew their petition to be afforded, under 35 U.S.C. §§ 120 and 365(a), a claim of domestic priority to PCT International Patent Application No. PCT/EP2003/50201, and through this international application, pursuant to 37 C.F.R. § 1.55(c) and under 35 U.S.C. §§ 119(a)-(d) and 365(b), a claim of foreign priority to EP02077953.4. Applicants respectfully submit that the showing above with regard to the claim for domestic priority of PCT/EP2003/50201 adequately establishes the basis of the applicants' claim to that domestic priority. With regard to applicants' petition under 37 C.F.R. § 1.55(c) for a foreign priority claim under 35 U.S.C. §§ 119(a)-(d) and 365(b) as to EP02077953.4, the applicants submit as follows:

1. Applicants' application was filed on August 20, 2003, and was accordingly filed after November 29, 2000. Therefore, the applicants' claims are submitted after the expiration of the periods specified in 37 C.F.R. § 1.55(c). It follows that the instant petition is proper under 37 C.F.R. § 1.55(c).
2. The reference to EP02077953.4, the prior filed foreign application for which priority is claimed, has been properly made by identifying the application number, country and filing date of that application in the Declaration filed on November 20, 2006, in the instant application.
3. The surcharge required under 37 C.F.R. § 1.17(t) was previously submitted in conjunction with applicants' prior Petition dated November 16, 2006.
4. Applicants hereby state that the entire delay between the date the claim was due under 37 C.F.R. §§ 1.78(a)(2)(ii) and 1.78(a)(5)(ii) and the date that the claim was filed was unintentional.
5. The application, through which the present foreign priority claim is made, namely International Patent Application No. PCT/EP2003/50201, was filed within 12 months of the filing date of EP02077953.4. International Patent Application No. PCT/EP2003/50201 was filed on May 27, 2003. EP 02077953.4 was filed less than eleven months earlier on July 18, 2002. It follows that International Patent Application No. PCT/EP2003/50201 was filed within 12 months of the filing date of EP02077953.4.

In view of the prior indications of the Legal Examiner that a valid foreign priority claim to EP02077953.4 would exist provided that a proper domestic priority claim was established for International Patent Application No. PCT/EP2003/50201, further given the applicants' showing that such a domestic priority claim is factually and legally supported, and finally given the showing above that the instant Petition satisfies the conditions of 37 C.F.R. § 1.55(c), the

applicants respectfully submit that the foreign priority claim under 35 U.S.C. §§ 119(a)-(d) and 365(b) to EP02077953.4 should now be in acceptable form. Reconsideration of the petition with respect to this priority claim is therefore requested.

**Authorization to Charge Deposit Account**

Applicants note that, pursuant to 37 C.F.R. § 1.78(a)(3), the required surcharge set forth in § 1.17(t) was submitted in conjunction with the communication filed November 16, 2006. However, any fee required but not submitted with this communication may be charged to deposit account no. 20-1469.

## CONCLUSION

Acceptance of the applicants' claim of domestic priority under 35 U.S.C. §§ 120 and 365(c) to PCT International Patent Application No. PCT/EP2003/007690 and International Patent Application No. PCT/EP03/50201 is requested. Acceptance of the applicants' claim to domestic priority under 35 U.S.C. §§ 119(e) and 365(c) to United States Provisional Application Serial No. 60/397,066, and their claim of foreign priority under 35 U.S.C. § 119(a)-(d) to European Patent Application No. 02077953.4 are also respectfully requested. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by telephone conference, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Alexander T. Stein, Ph.D.

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Enclosure: Amendment

Date: September 1, 2010

ATS/ats

**COPY**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Jones et al.

**Serial No.:** 10/644,256

**Filed:** August 20, 2003

**For:** EFFICIENT PRODUCTION OF IgA  
IN RECOMBINANT MAMMALIAN  
CELLS

**Confirmation No.:** 6153

**Examiner:** M. Joike

**Group Art Unit:** 1636

**Attorney Docket No.:** 2578-6077US

**NOTICE OF EXPRESS MAILING**

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**AMENDMENT UNDER 37 C.F.R. § 1.114**

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Responsive to the Final Office Action of March 15, 2010, and the Advisory Action of August 30, 2010, please amend the referenced patent application as follows:

**Amendments to the Specification** appear on page 2 of this paper;

**Amendments to the Claims** are set forth in the listing of the claims that begins on page 3 of this paper; and

**Remarks** start at page 7 of this paper.

**IN THE SPECIFICATION:**

Please amend paragraph [0001] as follows:

[0001] This application is a continuation-in-part of U. S. Patent Application Serial No. 09/549,463, filed April 14, 2000, now U.S. Patent 6,855,544 B1, the contents of the entirety of which is incorporated herein by this reference, which US Application Serial No. 09/549,463 application claims the benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 60/129,452, filed April 15, 1999. The instant ~~This~~ application is also a continuation-in-part of co-pending PCT International Patent Application No. PCT/EP2003/007690, filed on July 15, 2003, designating the United States of America, and published, in English, as International Publication No. WO 2004/009618A2 ~~WO 2004/009618 A2~~ on January 29, 2004, which International Patent Application claims the benefit under 35 U.S.C. § 119(e) to U.S. Provisional Application No. 60/397,066, filed July 18, 2002. The instant application is also a continuation-in-part of co-pending International Patent Application No. PCT/EP03/50201, filed May 27, 2003, designating the United States of America, which International Patent Application claims the benefit under 35 U.S.C. § 365(b) to European Patent Application No. 02077953.4, filed July 18, 2002, and further claims the benefit under 35 U.S.C. §119(e) to U.S. Provisional Application No. 60/397,066, filed July 18, 2002. ~~of PCT International Patent Application No. PCT/EP03/50201, filed May 27, 2003, European Patent Application No. 02077953.4, filed July 18, 2002, and United States Provisional Patent Application Serial No. 60/397,066, filed July 18, 2002.~~

**IN THE CLAIMS:**

Claims 2-5, 13, and 21 were previously canceled. Claim 9 is cancelled herein. Claims 1, 8, and 10 have been amended herein. All of the pending claims are presented below. This listing of claims will replace all prior versions and listings of claims in the application. Please enter these claims as amended.

**Listing of the Claims:**

1. (Currently amended) A cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid comprising a selectable marker, said recombinant nucleic acid further encoding an IgA molecule in expressible format, wherein said cell is derived from a human embryonic retinoblast cell as deposited under ECACC number 96022940 by stable transfection of said human embryonic retinoblast cell with the recombinant nucleic acid encoding the IgA molecule in expressible format, ~~wherein stable transfection may be determined by selecting those transfected human embryonic retinoblast cells capable of surviving growth in a media selective for the presence of the selectable marker for a predetermined amount of time wherein said cell, when seeded at  $0.5 \times 10^6$  cells/well and cultured in 6-well tissue culture plates at 37 °C in DMEM with 10% serum under an atmosphere containing 10% CO<sub>2</sub>, produces at least 5 pg IgA/seeded cell/day.~~

2.-5. (Cancelled).

6. (Original) The cell of claim 1, wherein said cell comprises between one and twenty copies of said recombinant nucleic acid encoding the IgA molecule.

7. (Original) The cell of claim 1, wherein said IgA molecule is a human IgA molecule.



8. (Currently amended) A cell expressing E1A and E1B proteins of an adenovirus, said cell comprising a selectable marker, said recombinant nucleic acid further comprising recombinant nucleic acid encoding an IgA molecule in expressible format, wherein said cell is derived from a human embryonic retinoblast cell as deposited under ECACC number 96022940 by stable transfection of said human embryonic retinoblast cell with the recombinant nucleic acid encoding the IgA molecule in expressible format, and wherein said IgA molecule has a constant region comprising amino acids 137 to 489 of SEQ ID NO:3, wherein stable transfection may be determined by selecting those transfected human embryonic retinoblast cells capable of surviving growth in a media selective for the presence of the selectable marker ~~for a predetermined amount of time.~~

9. (Cancelled).

10. (Currently amended) The cell of ~~claim 9~~ claim 1, wherein said cell, when seeded at  $0.5 \times 10^6$  cells/well and cultured in 6-well tissue culture plates at 37°C in DMEM with 10% serum under an atmosphere containing 10% CO<sub>2</sub>, produces at least 20 pg IgA/seeded cell/day.

11. (Previously presented) The cell of claim 10, wherein said cell, when seeded at  $0.5 \times 10^6$  cells/well and cultured in 6-well tissue culture plates at 37°C in DMEM with 10% serum under an atmosphere containing 10% CO<sub>2</sub>, produces at least 40 pg IgA/seeded cell/day.

12. (Withdrawn) A method for recombinant production of an IgA molecule, said method comprising:

culturing a cell of claim 1, and  
expressing said recombinant nucleic acid encoding an IgA molecule,  
thus producing an IgA molecule.

13. (Cancelled).

14. (Withdrawn) The method according to claim 12, wherein said cell has from one to twenty copies of said recombinant nucleic acid encoding the IgA molecule.

15. (Withdrawn) The method according to claim 12, wherein said IgA molecule is a human IgA molecule.

16. (Withdrawn) The method according to claim 12, wherein said IgA molecule has a constant region comprising amino acids 137 to 489 of SEQ ID NO:3.

17. (Withdrawn) The method according to claim 12, wherein said cell is seeded at  $0.5 \times 10^6$  cells/well and cultured in 6-well tissue culture plates at 37°C in DMEM with 10% serum under an atmosphere containing 10% CO<sub>2</sub>, thus producing at least 5 pg IgA/seeded cell/day.

18. (Withdrawn) The method according to claim 12, wherein said cell is seeded at  $0.5 \times 10^6$  cells/well and cultured in 6-well tissue culture plates at 37°C in DMEM with 10% serum under an atmosphere containing 10% CO<sub>2</sub>, thus producing at least 20 pg IgA/seeded cell/day.

19. (Withdrawn) The method according to claim 12, wherein said cell is seeded at  $0.5 \times 10^6$  cells/well and cultured in 6-well tissue culture plates at 37°C in DMEM with 10% serum under an atmosphere containing 10% CO<sub>2</sub>, thus producing at least 40 pg IgA/seeded cell/day.

20. (Withdrawn) A process for recombinantly producing a human IgA molecule, said process comprising:

culturing the cell of claim 1, wherein said cell comprises recombinant nucleic acid encoding a human IgA molecule in expressible format, and

expressing said recombinant nucleic acid encoding an IgA,

thus producing a human IgA molecule.

21. (Cancelled).

22. (Previously presented) A cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format, wherein said cell is derived from a human embryonic retinoblast cell as deposited under ECACC number 96022940 by transfection of said human embryonic retinoblast cell with the recombinant nucleic acid encoding the IgA molecule in expressible format, wherein the cell expresses E1A and E1B proteins of an adenovirus after 3 weeks in culture.

23. (Previously presented) A cell expressing E1A and E1B proteins of an adenovirus, said cell comprising between one and about 20 copies of recombinant nucleic acid encoding an IgA molecule in expressible format, wherein said cell is derived from a human embryonic retinoblast cell as deposited under ECACC number 96022940 by transfection of said human embryonic retinoblast cell with the recombinant nucleic acid encoding the IgA molecule in expressible format, wherein the nucleic acid encoding an IgA molecule is not amplified within the cell.

## REMARKS

The Final Office Action of March 15, 2010, and the Advisory Action of August 30, 2010, have been received and reviewed. Claims 1, 6-11, 22, and 23 stand rejected. This application is to be amended as previously set forth. All claim cancellations and amendments are made without prejudice or disclaimer. Basis for the amendments can be found throughout the application; for example, in the previously presented claims, and in the Specification at, *e.g.*, **Examples I and II**. No new matter has been presented. Reconsideration is respectfully requested.

### Telephone Interviews

Applicants appreciate the courtesy extended by the Examiner during the telephone interview of August 27, 2010. Alexander T. Stein, attorney for the applicants, sought clarification from the Examiner regarding the basis for the dismissal of the applicants' petition for acceptance of unintentionally delayed priority claims, as the Decision on Second Renewed Petition of August 23, 2010, referenced an Advisory Action that had not at that time been mailed to the applicants. Examiner Joike indicated that the Advisory Action had been prepared and would be mailed to the applicants. Examiner Joike also communicated the substance of the Advisory Action to Dr. Stein. Dr. Stein expressed concern that the Final Office Action and the Decision on Second Renewed Petition could be read together to suggest a situation where: a) the Examiner could not enter an amendment incorporating a priority claim reference to the application until a petition for acceptance of that unintentionally delayed priority claim had been granted; and b) the Office could not grant the applicants' petition for acceptance of an unintentionally delayed priority claim until a priority claim reference had been entered into the application by amendment. Examiner Joike clarified that once the applicants filed a Request for Continued Examination (RCE), the proposed amendment to the Specification could be entered and the petition decided.

Applicants further appreciate the courtesy extended by Richard M. Ross of the U.S.P.T.O. Office of PCT Legal Administration during the telephone interview of August 31, 2010. Alexander T. Stein, attorney for the applicants, sought to verify that the applicants' petition for

the acceptance of unintentionally delayed priority claims could be granted after the filing of an RCE. Mr. Ross indicated that, if all the supporting documents were in order, the applicants' petition would be granted after prosecution had been reopened by the filing of an RCE.

The applicants believe that the foregoing adequately describes both interviews. If, however, the Office believes more detail to be desirable, the Office is kindly requested to contact the applicants' attorney, and more detail will be provided to the extent available.

### **Priority**

The present application continues to claim priority to U.S. Patent Application Serial No. 09/549,463, filed April 14, 2000, now U.S. Patent 6,855,544 B1; U.S. Provisional Patent Application Serial No. 60/129,452, filed April 15, 1999; PCT International Patent Application No. PCT/EP2003/007690, filed July 15, 2003, designating the United States of America, and published, in English, as International Publication No. WO 2004/009618A2 on January 29, 2004; U.S. Provisional Application No. 60/397,066, filed July 18, 2002; co-pending International Patent Application No. PCT/EP03/50201, filed May 27, 2003, designating the United States of America; European Patent Application No. 02077953.4, filed July 18, 2002; and U.S. Provisional Application No. 60/397,066, filed July 18, 2002.

The Office has noted that the applicants must file a petition for acceptance of unintentionally delayed priority claims in order for the present application's priority claims to be entered. Final Office Action, at pages 2-3. Applicants filed such a petition in the Office concurrently with an Amendment under 37 C.F.R. § 1.116 on May 17, 2010. As explained in the Decision on Second Renewed Petition of August 23, 2010, the applicants' petition cannot be granted by the U.S.P.T.O. Office of PCT Legal Administration until the applicants have reopened prosecution so that appropriate references to the priority documents can be added to the application. Id. Consequently, the applicants have now filed a Request for Continued Examination and the present Amendment requesting entry of the appropriate references into the application. The applicants have also filed a Renewed Petition under 37 C.F.R. § 1.78(a)(3), a copy of which is provided herewith as a courtesy to the Office.

The applicants most respectfully request that the amendments to the Specification set

forth in this Amendment be entered. The applicants respectfully submit that these amendments introduce appropriate references to priority documents into the application, and that the Office will be in a position to grant the applicants' priority claims once the applicants' renewed petition has been granted.

**Objection to the Specification**

The Specification stands objected to as containing priority references to PCT International Application Nos. PCT/EP03/007690 and PCT/EP03/50201, European Patent Application No. 02077953.4, and U.S. Provisional Patent Application Serial No. 60/397,066, which priority claims have not been granted. Final Office Action, at page 2. Applicants duly note the objection, and respectfully submit that the objection will become moot when the concurrently-submitted petition for amended priority rights under 37 C.F.R. §§ 1.78(a)(3), 1.78(a)(6), and 1.55(c) is granted. Applicants have submitted an amendment to the Specification with the present Amendment to comply with the Office's request. See Decision on Renewed Petition of March 9, 2010, at page 2.

**Oath/Declaration**

The Office asserts that the Declaration of November 20, 2006, is without effect, for the reason that a priority claim under 37 C.F.R. § 1.55 to an identified foreign application has not been made. Final Office Action, at pages 3-4. As set forth, *supra*, the concurrently-submitted petition will render this objection moot.

**35 U.S.C. § 112, first paragraph**

Claims 1 and 6-11 stand rejected under 35 U.S.C. § 112, first paragraph, for assertedly failing to comply with the written description requirement. Final Office Action, at page 4. Specifically, the Office asserts that, while there is support in the Specification for "various, specified times," there is "no support in the specification for a predetermined amount of time." Id. Claim 9 has been canceled, rendering the rejection of this claim moot. Without agreeing that the Specification does not provide ample description of selection for stable transfectants by

growth in selective media for predetermined times, the applicants have amended independent claims 1 (from which claims 6 and 7 depend) and 8 (from which claims 10 and 11 depend) to remove recitation of “for a predetermined amount of time.” For at least this reason, the applicants respectfully request the rejection of claims 1, 6-8, 10, and 11 under 35 U.S.C. § 112, first paragraph, be withdrawn.

**35 U.S.C. § 112, second paragraph**

Claims 1 and 6-11 stand rejected under 35 U.S.C. § 112, second paragraph, for assertedly being indefinite. Final Office Action, at page 4. Specifically, the Office asserts that the term, “predetermined amount of time,” is vague. Id. Applicants do not agree that “predetermined amount of time” renders claims 1 and 6-11 indefinite; for example, one of ordinary skill in the art would know what is meant by selecting transfectants with a selectable marker by growth in selective media for a predetermined amount of time. Applicants have canceled claim 9, rendering the rejection of this claim moot. And, the applicants have amended the remaining claims, as set forth, *supra*, to remove recitation of “for a predetermined amount of time.” For at least this reason, the applicants respectfully request the rejection of claims 1, 6-8, 10, and 11 under 35 U.S.C. § 112, second paragraph, be withdrawn.

**35 U.S.C. § 103**

Claims 1, 6, and 7 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over U.S. Patent 6,821,512 to Gao *et al.* (hereinafter “the ‘512 Patent”) in view of International PCT Publication WO 00/63403 by Hateboer *et al.* (hereinafter “the ‘403 publication”). Final Office Action, at pages 5-7. Applicants respectfully traverse the rejection.

Applicants note that claim 9 was not subject to the rejection under 35 U.S.C. § 103(a). Without agreeing that any of claims 1, 6, and 7 are obvious in view of the cited references, the applicants have amended independent claim 1 (from which claims 6 and 7 depend) to incorporate the subject matter of claim 9. For at least this reason, the applicants respectfully request the rejection of claims 1, 6, and 7 under 35 U.S.C. § 103(a) be withdrawn.

**Nonstatutory double patenting rejection**

Claims 1, 6, and 7 stand rejected on the grounds of non-statutory obviousness-type double patenting as being assertedly unpatentable over claims 1, 3, 6-7, and 9 of U.S. Patent No. 7,429,486 ('486 Patent). Further, claims 1, 6, and 7 stand rejected on the grounds of nonstatutory obviousness-type double patenting as being assertedly unpatentable over claims 1, 2, and 5-7 of U.S. Patent No. 7,262,028 ('028 Patent).

Applicants note that claim 9 was not subject to a non-statutory obviousness-type double patenting rejection over either the '486 Patent or the '028 Patent. Without agreeing that any of claims 1, 6, and 7 are not patentably distinct from the claims of either patent, the applicants have amended claim 1 (from which claims 6 and 7 depend) to incorporate the subject matter of claim 9. For at least this reason, the applicants respectfully request the non-statutory obviousness-type double patenting rejections of claims 1, 6, and 7 be withdrawn.

Claims 1, 6, 7, 22, and 23 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being assertedly unpatentable over the claims of co-pending application 12/291,881 (hereinafter "the '881 application") in view of Gao *et al.* Pursuant to MPEP § 804(I)(B)(1), the applicants respectfully submit this provisional rejection should be withdrawn, at least in view of the fact that the present application has an earlier filing date than the '881 application. The '881 application has a filing date of November 14, 2008. The present application has a filing date of August 20, 2003.

As provided for in the MPEP § 804(I)(B)(1),

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can



be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based upon the other two, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

Id. (Emphasis added).

Accordingly, applicants respectfully request that the Office withdraw the provisional obviousness-type double patenting rejection based upon the '881 application.

### **Rejoinder**

Applicants respectfully request rejoinder of claims 12 and 14-20. If an applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims which depend from, or otherwise include all elements of the allowable product claim, will be rejoined. MPEP § 821.04. Applicants respectfully submit that claims directed to a product (*e.g.*, claim 1) were previously elected by the applicants. Applicants currently believe the product claims to be in condition for allowance in view of the present amendments. As such, applicants respectfully request rejoinder of process claims 12 and 14-20, which include all the elements of an allowable product claim.

**Serial No. 10/644,256**

In view of the foregoing amendments and remarks, the application is believed to be in condition for allowance. If questions remain after consideration of the foregoing, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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Date: September 1, 2010  
ATS/ats

Enclosure: Petition for Acceptance of Unintentionally Delayed Priority Claims